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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,554	04/09/2004	Yuuki Watanabe	09792909-5863	1305

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EXAMINER

LUM, LEON YUN BON

ART UNIT PAPER NUMBER

1641

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,554

Applicant(s)

WATANABE, YUUKI

Examiner

Leon Y. Lum

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-11 are objected to because of the following informalities: the phrase "using spatial structure" in line 6 seems to be either missing at least one term that would clarify the claimed "detecting portion." Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 1 and 12-18 each recite the limitation "the presence/absence, distribution, and so on, of the target." The claims are vague and indefinite for the following reasons:
 - a. It is unclear whether (1) a presence, (2) an absence, or (3) both a presence and an absence, is claimed by the term "presence/absence."

b. A term or phrase (i.e. "or", "consisting of", "comprising of") indicating that the limitations "presence/absence", "distribution", "and so on" are either (1) all required or (2) claimed in the alternative, is lacking. It is therefore unclear whether all the limitations are claimed together, or claimed alternatively.

c. The phrase "and so on" is vague and indefinite. The specification does not define the phrase and one of ordinary skill in the art at the time of the invention would not recognize what is claimed by the phrase.

5. In claim 5, lines 2-3, the phrase "in alignment with sizes of the targets" is vague and indefinite. The specification provides support for this phrase on page 6. However, it is unclear how the binding sites are specifically arranged to induce the effect of "detect[ing] changes in amount of the targets with time." Since the claim seems to be comparing the binding sites with their targets, it is also unclear how the binding sites are arranged relative to each other.

6. Claim 11 recites the limitation "the relation" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

7. In claim 12, line 4, the phrase "a plural pieces" is vague and confusing. The phrase seems to indicate both a singular and plural embodiment at the same time, and it is unclear as to how much "information" (line 4) is being claimed.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5 and 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamentsky (US 4,487,839).

Kamentsky teaches an immunoassay comprising antibodies immobilized in a particularized pattern on a substrate (i.e. biological substance sensor; using spatial structure of the detecting portion), wherein the pattern is a repetitive pattern (i.e. spatial structure is a geometrical structure; plurality of binding sites), and wherein immunological reactions between the antibodies and antigens in a sample will occur substantially only in the regions of the substrate comprising the antibodies. A detector used for measuring the reactions will detect a repetitive signal that can be analyzed electronically and/or mathematically to determine the quantity of antigens originally present in the sample (i.e. plural pieces of information including information about the presence and distribution of the target). See column 1, lines 40-66. The combination of a “repetitive pattern” and “quantity of antigens” is considered to read on the claimed “plural pieces of information.”

In regards to claim 4, Kamentsky teaches that different areas of the surface can be coated with various types of antibodies or multiple controls (i.e. plurality of binding

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sites permitting a plurality of targets to selectively couple therewith.) See column 4, lines 26-31.

In regards to claims 15-18, Kamentsky teaches serum antibodies (i.e. secretion produce) specific for cellular antigens (i.e. secretion sensor device and method; emotion sensing device and method). See column 5, lines 31-34. Although the preambles between apparatus claims 15 and 17 and between method claims 16 and 18 differ, since the embodiments of both apparatus claims and the active step of both method claims require the same "secretion product," each of the two sets of claims are considered to claim the same subject matter.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamentsky (US 4,487,839) in view of Kornguth et al (US 5,629,213).

The teachings of Kamentsky are disclosed above, but fail to describe an apparatus that is capable of extracting said information by measuring changes in dielectric constant of the detection portion upon coupling with the targets according to the principle of surface plasmon resonance.

Kornguth et al teach a biosensor system utilizing SPR, in order to detect analytes without requiring extra steps involved with labeling. See column 1, lines 15-34 and 55-60; column 2, lines 29-40.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kamentsky by utilizing SPR, as taught by Kornguth et al, in order to detect analytes without requiring extra steps involved with labeling. The advantage of a quicker detection technique provides the motivation to combine the teachings of Kamentsky and Kornguth et al. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in applying the SPR detection technique of Kornguth et al to the biosensor of Kamentsky, since Kamentsky teaches immunoassays on a planar substrate, and the SPR technique of Kornguth et al is fully capable of detecting binding interactions on a planar substrate. See column 2, lines 29-32.

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13. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamentsky (US 4,487,839) in view of Willner et al (US 6,630,309 B2).

The teachings of Kamentsky are disclosed above, but fail to describe an apparatus that is capable of extracting said information by measuring changes in weight of the detection portion upon coupling with the targets by using an oscillating circuit and a frequency measuring device.

Willner et al teach piezoelectric detection devices, in order to detect interactions between two members of a recognition pair, in order to provide a detection technique that does not rely on the need for labeling.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Kamentsky by using piezoelectric detection devices, as taught by Willner et al, in order to provide a detection technique that does not rely on the need for labeling. The advantage of a quicker detection technique provides the motivation to combine the teachings of Kamentsky and Willner et al. In addition, one of ordinary skill in the art at the time of the invention would have had a reasonable expectation of success in applying the piezoelectric detection technique of Willner et al to the biosensor of Kamentsky, since Kamentsky teaches immunoassays on a planar substrate, and the piezoelectric detection technique of Kornguth et al is fully capable of detecting binding interactions on planar substrates.

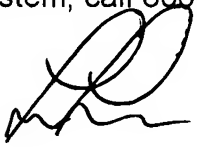
Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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